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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/532,716

11/16/2005

Henrik Leisner

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JACOBSON HOLMAN PLLC
400 SEVENTH STREET N.W.
SUITE 600
WASHINGTON, DC 20004

EXAMINER

ANDERSON, CATHARINE L

ART UNIT

PAPER NUMBER

3761

MAIL DATE

DELIVERY MODE

05/12/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/532,716	Applicant(s) LEISNER, HENRIK	
	Examiner Lynne Anderson	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6-9 and 12-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6-9 and 12-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1, 3-4, 6-9, and 12-24 have been considered but are moot in view of the new ground(s) of rejection.
2. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the first and second tensile strengths being different from one another) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).
3. The present claims do not positively recite that the first and second tensile strengths must be different from one another, and therefore it is within the scope of the present claims that the first and second tensile strengths are of the same value.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 6, 9, 13, and 23-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuczynski (5,722,965).
6. Kuczynski discloses an ostomy device, as shown in figure 1, comprising a body side member 14 and a collecting bag 12. The body side member 14 comprises a first

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flange 76, as shown in figure 9. The collection bag 12 includes a coupling element 50, as shown in figure 9, comprising a second flange 60. A flexible layer 84 is bonded to the first flange 76, as shown in figure 9, and the bond between the flexible layer 84 and the first flange 76 is stronger than the adhesive connection between the first flange 76 and the coupling element 50, since the flexible layer 84 remains bonded to the first flange 76 when the coupling element 50 is removed, as shown in figure 10 and disclosed in column 6, lines 53-65. The flexible layer 84 therefore also has a yield strength that is greater than the adhesive strength of the adhesive layer 62. The first flange 76 and the second flange 60 comprise the identical foam material, as disclosed in column 4, lines 33-36, and column 5, lines 35-38, and therefore have the same tensile strength. The flexible layer 84 comprises a film layer, as disclosed in column 6, lines 4-8.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 3-4, 7-8, 12, and 14-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuczynski (5,722,965).

9. With respect to claim 3, Kuczynski remains silent as to the connecting strength and the yield strength between the flexible layer and the flanges. Kuczynski teaches the desire for only the first flange to remain attached to the base plate when the ostomy

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bag is separated, as disclosed in column 6, lines 53-65. To allow for the removal of the ostomy bag without removal of the base plate at the same time, it would be obvious to one of ordinary skill in the art at the time of invention to provide the device with a connection strength between the flexible layer and the second flange than exceeds the adhesive strength, so that the adhesive releases the flexible layer and second flange, thereby allowing the ostomy bag comprising the second flange to be removed from the base plate. Likewise, it would have been obvious for the yield strength of the flexible layer to have the same order of magnitude as the first flange, to allow the flexible layer and the first flange to be separated, so the ostomy bag may be removed without removal of the base plate comprising the first flange.

10. With respect to claims 4, 8, and 12, Kuczynski remains silent as to the elastic modulus of the flexible layer and the flanges. Kuczynski teaches the need for the first flange to be more resilient during deformation than the second flange, as shown in figure 10. In order to provide a material having a greater resiliency, it would be obvious to one of ordinary skill in the art at the time of invention to provide the flange of Kuczynski with a greater elastic modulus so as to allow for a resilient, deformable flange.

11. With respect to claims 7 and 14-22, Kuczynski discloses all aspects of the claimed invention with the exception of the tensile strength of the first flange being greater than the tensile strength of the second flange. Kuczynski teaches the need for the second flange to be deformable during removal of the ostomy bag, as shown in figure 10. It would therefore be obvious to one of ordinary skill in the art at the time of

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invention to provide the second flange of Kuczynski with a lower tensile strength than the first flange to provide the predictable result of a softer, more deformable flange to ease in the removal of the ostomy bag.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynne Anderson whose telephone number is (571)272-4932. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/L. A./

Examiner, Art Unit 3761

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761